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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/974,519	10/10/2001	Dhiren R. Thakker	421/32/2	7285
25297	7590	08/22/2006	EXAMINER	
JENKINS, WILSON, TAYLOR & HUNT, P. A. 3100 TOWER BLVD SUITE 1200 DURHAM, NC 27707				GRAFFEO, MICHEL
ART UNIT		PAPER NUMBER		
		1614		

DATE MAILED: 08/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/974,519	THAKKER ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Michel Graffeo	1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 12 May 2006.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,6 and 8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,6 and 8 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

**DETAILED ACTION**

***Status of Action***

Claims 1, 6 and 8 are examined.

Applicant has amended claim 1, canceled claim 2 and provided arguments for the patentability of claims 1, 6 and 8 in the response filed 12 May 2006.

Applicant's arguments, see response, filed 12 May 2006, have been fully considered and are persuasive to the extent that the objection to the IDS is withdrawn. Any rejection not specifically stated in this Office Action has been withdrawn.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 6 and 8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 as amended limits the class of phospholipase C to those selected from the group of alkylphosphocholines having a straight-chain alkyl of 13 to 20 methylene groups. In comparison, the instant

Specification describes an applicable group of phospholipase C inhibitors having 9-20 alkyl groups (see page 5 lines 18-25). Thus, the narrowed class of actives is new matter.

***Claim Rejections - 35 USC § 102***

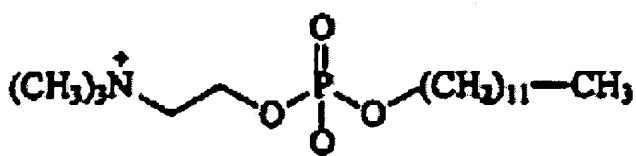
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Liu et al. 88 J Pharmaceutical Sci 1161-1168.

Liu et al. teach that DPC can improve the paracellular permeability of certain compounds across the intestinal epithelium (in current claims 1-2 and 6; see Abstract). DPC is shown as having the following structural formula (in current claim 2; see page 1162):



**Dodecylphosphocholine (DPC)**

***Claim Rejections - 35 USC § 103***

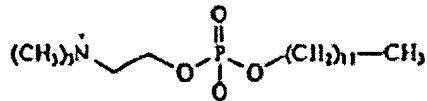
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liu et al. 88 J Pharmaceutical Sci 1161-1168.

Liu et al. teach that DPC can improve the paracellular permeability of certain compounds across the intestinal epithelium (in current claims 1-2 and 6; see Abstract). DPC is shown as having the following structural formula (in current claim 2; see page 1162):



Dodecylphosphocholine (DPC)

Although Liu et al. do not specifically recite the administration of the claimed actives to a patient, but does teach that the intent of such administration is to facilitate permeability of the intestines. To this extent, it is obvious to one of ordinary skill in the art to dose/administer the actives via a mechanism, most of which are listed in claim 8. Thus, the reference suggests and makes *prima facie* obvious how to use the claimed invention at the time that it was made.

#### ***Response to Arguments***

Applicant's arguments filed 12 May 2006 have been fully considered but they are not persuasive. Primarily, DPC comprises 14 methyl groups in a straight chain. As amended the claim language does not limit the methyl groups such that they must all be linked together.

Liu et al. specifically recite the efficacy of the actives and include DPC (which is a preferred embodiment; see instant Specification on page 17 lines 20-end). Examiner points to the Abstract which is copied below:

junctions. In this report we show that dodecylphosphocholine (DPC) can improve the paracellular permeability of hydrophilic compounds across Caco-2 cell monolayers by modulating the tight junctions. The

That the reference as a whole does not teach PLC inhibition is of no moment primarily since PLC inhibition is not recited in the claim. Claim 1 only recites the administration of a PLC inhibitor, of which DPC is as per the instant Specification.

***Conclusion***

No claim is allowed.

Applicant's amendment, the addition of the limitation in claim 1, necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michel Graffeo whose telephone number is 571-272-8505. The examiner can normally be reached on 9am to 5:30pm Monday to Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

15 August 2006  
MG

*Ardin H. Marschel 8/17/06*  
**ARDIN H. MARSCHEL**  
**SUPERVISORY PATENT EXAMINER**